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PHILIPS

Philips Medical Systems

K003459

510 (k) Summary

Philips "MR Quantitative Flow" Software package

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I General Information

Company Name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue Shelton, CT 06484
Contact Person	Peter Altman
Telephone Number:	203-926-7031
Prepared (date):	November 03, 2000
Device Name:	Philips Easy Vision Family Workstation Option MR Quantitative Flow
Classification Name:	Magnetic resonance diagnostic device 892.1000
Classification:	Class II
ProCode:	90 LNH
Common/Usual Name:	Workstation
Predicate Devices:	Philips Easy Vision Workstation

Philips Medical Systems
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II Information Supporting Substantial Equivalence Determination

System Description:

This submission for the MR Quantitative Flow package adds capabilities to the existing Philips EasyVision Family of workstations using images acquired from MR systems. The MR Quantitative Flow package allows the user to analyse velocity encoded acquired MRI datasets to show flow and flow velocity.

Intended Use:

The MR Quantitative Flow option is intended to be used to analyse velocity encoded MRI datasets in order to provide results relating to blood flow within user prescribed Regions of Interest (ROI). Results include: stroke volume, forward flow volume, backward flow volume, absolute flow volume, flux, stroke distance, mean velocity, maximum velocity, minimum velocity, peak velocity and area. These results are intended to aid clinicians in the assessment of flow and flow velocity in vessels and heart valves

Safety information:

No new hazards are introduced by the addition of the MR Quantitative Flow Option to the EasyVision Workstation

Substantial equivalence:

The Philips EasyVision MR Quantitative Flow package is substantially equivalent to the MEDIS Medical Imaging Systems, B.V, MRI – FLOW analytical software package (K994282) and the Picker International, Inc Quantitative Flow package (K992225).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2001

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
SHELTON CT 06484

Re: K003459
Philips Easy Vision Family Workstation Option
MR Quantitative Flow
Dated: November 6, 2000
Received: November 7, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Altman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(K) Number (if known): ~~Unknown~~ K003459

Device Name: Philips EasyVision MR Quantitative Flow Option

Indications for Use:

The MR Quantitative Flow option is intended to be used to analyse velocity encoded MRI datasets in order to provide results related to blood flow within user prescribed Regions of Interest (ROI). Analysis includes:

- User drawing of ROI's
- Using the phase information within the MRI data over time to calculate flow related results including : Results include : stroke volume, forward flow volume, backward flow volume, absolute flow volume, flux, stroke distance, mean velocity, maximum velocity, minimum velocity, peak velocity and area
- Displaying the results in charts and tables

Such results are intended to aid clinicians in the assessment of flow and flow velocity in vessels and across cardiac valves.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003459

(Optional Format 1-2-96)